DISTRICT OF COLUMBIA
OFFICE OF ADMINISTRATIVE HEARINGS
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Washington, DC 20002-4210

DISTRICT OF COLUMBIA DEPARTMENT OF HEALTH Petitioner, v. CVS PHARMACY #1335, 1344, 1343, and 1346 Respondent.	Case No.: DH-I-07-D100262 DH-I-07-D100263 DH-I-07-D100264 DH-I-07-D100278 (Consolidated)

FINAL ORDER RESOLVING ALL ISSUES EXCEPT CHARGE THREE OF NOTICE OF INFRACTION D100264[1]

I. INTRODUCTION

On September 11, 2007, an evidentiary hearing was held in these consolidated cases. The Government was represented by Thomas Collier, Esq. Janis Jackson, Pharmacist, testified on behalf of the Government. Respondent was represented by Edward Krill, Esq. Earl Ettienne, Senior Pharmacy Supervisor, appeared as corporate representative for Respondent. Before the Government could complete Ms. Jackson's direct examination, it became apparent that the parties' respective views of the issues in the cases were closer than first anticipated.

Consequently, after a break to allow the parties to talk, it was decided that Respondent would change its plea to many of the charges to Admit with Explanation, that

[1] Each notice of infraction alleged numerous violations of the governing regulatory scheme. In an attempt to simplify this Final Order, I have labeled each alleged violation a "charge" and assigned it a number which tracks chronologically the listing of charges in the relevant notice of infraction.

the Government would dismiss some of the charges and that the remaining charges would be resolved by the submission of pleadings. Based on the agreement of the parties, I entered a Briefing Schedule on September 12, 2007, affording Respondent until October 12, 2007, to file and serve its brief concerning all outstanding issues and the Government had until November 2, 2007, to file and serve its reply responsive pleading. Both parties filed pleadings in accord with this time frame.

Given Respondent's different pleas to the Charges in the four NOIs, the Government's decision to dismiss (see below) Charge 1 of NOI D100262 and NOI D100278 in its entirety, and my decision to require further development of the record on Charge 3 of NOI D100264 (see below), I will group my findings of fact and conclusions of law of the Charges by their resolution. In other words, I will group those Charges resolved by pleas of Admit with Explanation separate from those resolved by pleas of Deny, etc.

Based on the submissions of the parties and accepting the allegations of both parties as fact, as well as the entire record herein, I make the following findings of fact and conclusions of law.

II. FINDINGS OF FACT

A. Admits with Explanation

NOI D100263 – Charge 2

1. By way of its plea of Admit with Explanation, Respondent admits that on March 15, 2007, its records established that Respondent's pharmacist accepted three different prescriptions that did not conform to the governing regulatory scheme, in that the prescriptions were missing either the prescribing doctor's DEA controlled substances registration numbers ("DEA number"), or the doctor's name and signature.

2. One of these three prescriptions was written by a Georgetown Hospital resident. This prescription did not have the attending physician's name, signature or DEA number. Respondent's pharmacist obtained the requisite information by telephoning the attending physician and added the information to the container label. The other two prescriptions did not have the attending physicians' DEA numbers. Respondent's pharmacist also obtained this information by telephoning the doctor and then adding the information to the container label. Respondent's pharmacist deviated from the regulatory scheme in an attempt to assist the customers by preventing them from having to return to the doctor's office, have the prescription completed properly and then come back to the pharmacy in order to obtain their medication.

NOI D100263 – Charge 3

1. By way of its plea of Admit with Explanation, Respondent admits that on March 15, 2007, its records established that Respondent's pharmacist failed to record consistently the number of drug packages received and the dates these packages were received on DEA Form 222. In those instances when the pharmacist did not record the requisite data onto DEA Form 222, the pharmacist would attach the supplier's invoice to DEA Form 222. If accurate, the supplier's invoice does contain the information required for the DEA Form 222.

NOI D100264 – Charge 1

1. By way of its plea of Admit with Explanation, Respondent admits that on March 14, 2007, its records established that Respondent's pharmacist failed to record consistently the number of drug packages received and the dates these packages were received on DEA Form 222. In those instances when the pharmacist did not record the requisite data onto DEA Form 222, the pharmacist would attach the supplier's invoice to DEA Form 222. If accurate, the supplier's invoice does contain the information required for the DEA Form 222.

NOI D100264 – Charge 2

1. By way of its plea of Admit with Explanation, Respondent admits that on March 14, 2007, its records established that Respondent's pharmacist accepted two different prescriptions that did not conform with the governing regulatory scheme, in that the

prescriptions were missing either the prescribing doctor's DEA number, or the doctor's signature.

2. One of these two prescriptions was written by a physician at the Spine and Pain Center. This prescription did not have the attending physician's signature. Respondent's pharmacist obtained the requisite information by telephoning the attending physician and added the information to the container label. The other prescription did not have the attending physician's DEA number. Respondent's pharmacist also obtained this information by telephoning the doctor and then adding the information to the container label. Respondent's pharmacist deviated from the regulatory scheme in an attempt to assist the customers by preventing them from having to return to the doctor's office, have the prescription completed properly and then come back to the pharmacy in order to obtain their medication.

NOI D100262 – Charge 2

1. By way of its plea of Admit with Explanation, Respondent admits that on March 8, 2007, its records established that Respondent's pharmacist failed to record consistently the number of drug packages received and the dates these packages were received on DEA Form 222. In those instances when the pharmacist did not record the requisite data onto DEA Form 222, the pharmacist would attach the supplier's invoice to DEA Form 222. If accurate, the supplier's invoice does contain the information required for the DEA Form 222.

B. Denials

NOI D100262 – Charge 3

1. Respondent's practice is to return unclaimed prescriptions to its pharmacy stock. When returned to stock, the prescription container is relabeled "Return to Stock." The unclaimed prescriptions are not returned to the bulk containers from which the drugs were taken when the prescription was filled initially. When and if a customer presents a new prescription for that same drug, the medication is removed from the container with the "Return to Stock" label and dispensed to the new customer with a current (and proper) label. The original container is discarded. Respondent does not record the Lot Number on each prescription as it is taken from bulk containers.

NOI D100263 – Charge 1

1. Respondent's practice is to return unclaimed prescriptions to its stock in the pharmacy. When returned to stock, the prescription container is relabeled "Return to Stock." The unclaimed prescriptions are not returned to the bulk containers from which the drugs were taken when the prescription was filled initially. When and if a customer presents a new prescription for that same drug, the medication is removed from the container with the "Return to Stock" label and dispensed to the new customer with a current (and proper) label. The original container is discarded. Respondent does not record the Lot Number on each prescription as it is taken from bulk containers.

III. CONCLUSIONS OF LAW

A. Admits with Explanation

For clarity's sake, I have outlined in the chart below the NOIs (and specific Charges), as well as the associated regulation, fine amount (with citation to the regulation that authorizes the fine), Respondent's requested fine and the Government's recommended fine.

NOI & Charge	Regulation	Fine Amount	Respondent's Requested Fine	Government's Recommended Fine
NOI D100262 – Charge 2	22 DCMR 1503.1 and 21 CFR 1305.12	$2,000, pursuant to 16 DCMR 3616.1(h)	$500	$1,000
NOI D100263 – Charge 2	22 DCMR 1502.1, 1302.4, 1303.7(a), and 21 CFR 1306.5(a)	$2,000, pursuant to 16 DCMR 3616.1(g)	$100	$1,000
NOI D100263 – Charge 3	22 DCMR 1503.1	$2,000, pursuant to 16 DCMR 3616.1(h)	$500	$1,000
NOI D100264 – Charge 1	22 DCMR 1503.1 and 21 CFR 1305.12	$2,000, pursuant to 16 DCMR 3616.1(h)	$500	$1,000
NOI D100264 – Charge 2	22 DCMR 1502.1, 1301.2(b), 1301.2(d), and 21 CFR 1306.5(a)	$2,000, pursuant to 16 DCMR 3616.1(g)	$100	$1,000

There are no fines associated with violations of 22 DCMR Chapter 13. However, compliance with 21 CFR Part 13 is required by 22 DCMR 1502.1. As shown in the chart above, for each NOI in which the Government established that Respondent violated 22 DCMR Chapter 13, it also established that Respondent violated a provision of 22 DCMR Chapter 15, which shall govern fine calculations. The fines associated violations of 22 DCMR 1502.1 and 1503.1 are Class 1 infractions punishable by a $2,000 fine for a first offense. 16 DCMR 3201.1(c); 16 DCMR 3616.1(g) and 3616.1(h). In the NOIs, the Government requested fines totaling $10,000 for the 22 DCMR Chapter 15 violations.

In support of its proposed reductions in the fines for violations of 22 DCMR 1502.1[2], Respondent argued that the occurrences cited were rare and the pharmacist made good faith efforts to ensure that the prescriptions were valid. The Government responds by noting that given the danger of unregulated dispensation and use of these controlled substances, pharmacists do not have the discretion to confirm the validity of a prescription by calling the attending physician. The Government acknowledges that the governing regulations do allow pharmacists to dispense medications in an emergency situation; however, the pharmacists in these cases did not utilize those emergency procedures. I conclude that Respondent's acceptance of responsibility supports mitigation of the fines. Therefore, for NOIs D100263 – Charge 2 and D100264 – Charge 2, I impose a fine of $1,750 per violation for a total fine of $3,500.

[2] 22 DCMR 1502.1 reads:

> Every registrant shall keep records, maintain inventories and file reports in conformance with the requirements of federal law including the requirements prescribed under Part 1304, 21 CFR.

In support of its proposed reductions in the fines for violations of 22 DCMR 1503.1[3], Respondent argued that while it was not in technical compliance with the governing regulations, the required information (amounts shipped and date of receipt) was actually available on the supplier's invoice, which was attached to DEA Form 222. The Government responds by noting that these regulations are in place to control drugs and other substances "having a high potential for abuse," such that strict adherence to the controls is required and there is no place in the regulatory scheme for anything less than full compliance. I conclude that Respondent's corrective action taken, efforts to prevent future violations and good faith efforts to comply with the regulations all support fine mitigation. Therefore, for NOIs D100262 – Charge 2, D100263 – Charge 3, and D100264 – Charge 1, I impose a fine of $1,250 per violation for a total fine of $3,750.

B. Denials

Respondent maintained a plea of Deny for NOI D100262 – Charge 3, and NOI D100263 - Charge 1. For both Charges, the Government alleged that Respondent violated D.C. Code, 2001 Ed. § 47-2885.10(a)(3), 22 DCMR 1909.5 and 22 DCMR 1909.6 (in a manner similar to D.C. Code, 2001 Ed. § 47-2885.10(a)(3), 22 DCMR

[3] 22 DCMR 1503.2 reads:

> Accountability audits in pharmacies shall be accomplished through a review of invoices, prescription file, other records required by federal and District of Columbia laws and regulations, and this chapter.

1909.5 and 1909.6 prohibit the sale of adulterated drugs or devices).[4] For the reasons set forth below, I conclude that Respondent has not violated the governing regulatory scheme (D.C. Code, 2001 Ed. § 47-2885.10(a)(3), 22 DCMR 1909.5 and 22 DCMR 1909.6). Therefore, I am dismissing Charge 3 of NOI D100262 and Charge 1 of NOI D100263.

The uncontested evidence regarding these Charges was that if a prescription is not picked up by a customer, CVS affixes to the original container a new label that is marked "Return to Stock." The re-labeled container is then placed next to the bulk container of the same medicine. If a customer then submits a new prescription for the same medication, Respondent takes the medicine from the container labeled "Return to Stock," places the medication in a new container and then labels the new container appropriately. The Government asserts that this practice amounts to selling and dispensing drugs that are misbranded or adulterated. The Government's premise for this assertion is grounded on the uncontested fact that Respondent does not record the lot number of the bulk container from which the medication was taken, on each individual prescription container. Therefore, the argument goes, by failing to empty a prescription that is not picked up into the original bulk container; Respondent cannot track by lot number the medications that it has dispensed and returned to stock. The Government contends this is

[4] D.C. Code, 2001 Ed. § 47-2885.10(a)(3) reads:

> (a) The Mayor may refuse the issuance or renewal, or may revoke, or may suspend for not more than 90 days, a license issued pursuant to this part for any 1 or a combination of the following reasons:
>
> > (3) Selling, or offering for sale, adulterated or misbranded drugs or devices.

a problem because, for instance, if the manufacturer recalls a medication, Respondent will not know where it has dispensed the recalled drug(s).

The Government's argument has at least two fatal flaws (though I share the Government's concern about the inability to track by lot number the medications sold). The first weakness is the fact that the statute and the regulations cited in the NOIs do not require a pharmacy to record the manufacturer's lot number on individual prescription containers. Rather, as noted above, the statute and regulations cited in the NOI charge that Respondent violated provisions of the regulatory scheme that prohibit a pharmacy from selling or dispensing misbranded or adulterated drugs. *See* D.C. Code, 2001 Ed. § 47-2885.10(a)(3), 22 DCMR 1909.5 and 22 DCMR 1909.6. However, none of the evidence supports a conclusion that Respondent misbranded or sold adulterated drugs by restocking prescriptions that are not picked up by customers in the manner described above. Secondly, the problem, if one exists, is not due to Respondent's restocking procedures, but rather, the fact that Respondent (and apparently all pharmacies) does not record the manufacturer's lot number on individual prescription containers. Whether one of Respondent's customers failed to pick up a prescription, which was then returned to stock, has no bearing on Respondent's ability (or lack thereof) to identify which customers have medication that has been recalled by the manufacturer (the problem the Government seeks to avoid). If a manufacturer recalls a medication by lot number, Respondent will not be able to identify which customers have that drug – period (whether

or not the medication had ever been returned). As the Government has neither cited a statute or regulation that requires Respondent to record the lot number on each individual prescription container, nor proven by a preponderance of evidence that the drugs sold by Respondent are adulterated or misbranded, these charges must be dismissed.

C. Dismissals

As noted in my Order dated September 12, 2007, the Government has moved to dismiss Charge 1 in NOI D100262 and NOI D100278 in their entirety. I am dismissing these Charges with prejudice.

D. D100264 – Charge 3

In the NOI, the Government alleges that controlled substances on Schedule II were not properly accounted for during an audit, in violation of 22 DCMR 1503.1. Respondent denies this allegation on the belief that there was a misunderstanding of what was presented to the Inspector during the audit in question. In its Response, the Government declares that if a complete audit establishes that all controlled substances have been accounted for it will dismiss the charge. Therefore, I will order the parties to conduct a complete audit by a date certain.

Based on the submissions of the parties and the entire record herein, it is this 9th day of November 2007

ORDERED that Respondent CVS Pharmacies ##1335, 1343, 1344 and 1346 are **LIABLE** for violating 22 DCMR 1502.1 and 1503.1, as charged in Notices of Infraction No. D100262, D100263 and D100264; it is further

ORDERED that Respondent shall pay a fine in the amount of **SEVEN THOUSAND TWO HUNDRED FIFTY DOLLARS ($7,250**) in accordance with the attached instructions within twenty (20) calendar days of the date of mailing of this Order (15 calendar days plus 5 days for service by mail pursuant, to D.C. Code, 2001 Ed. §§ 2-1802.04 and 2-1802.05); it is further

ORDERED that, if Respondent fails to pay the above amount in full within 20 calendar days of the date of mailing of this Order, by law, interest shall accrue on the unpaid amount at the rate of 1½ %, or **ONE HUNDRED EIGHT DOLLARS ($108)**, per month or portion thereof, beginning with the date of this Order, pursuant to D.C. Code, 2001 Ed. § 2-1802.03(i)(1); it is further

ORDERED that failure to comply with the attached payment instructions and to remit a payment within the time specified will authorize the imposition of additional sanctions, including the suspension of Respondent's licenses or permits, pursuant to D.C. Code, 2001 Ed. § 2-1802.03(f), the placement of a lien on real or personal property owned by Respondent, pursuant to D.C. Code, 2001 Ed. § 2-1802.03(i), and the sealing of Respondent's business premises or work sites, pursuant to D.C. Code, 2001 Ed. § 2-1801.03(b)(7); it is further

ORDERED that Charges 1 and 3 of NOI D100262, Charge 1 of NOI D100263, and NOI D100278 in its entirety are **DISMISSED WITH PREJUDICE**; it is further

ORDERED that no later than Friday, December 21, 2007, the parties shall re-do the audit of controlled substances on Schedule II, as referenced in Charge 3 of NOI D100264, at CVS Pharmacy #1344; as well as submit a report indicating the results of the

audit and each party's recommendation as to how this Charge should be resolved by this administrative court; it is further

ORDERED that the appeal rights of any person aggrieved by this Order are stated below.

November 9, 2007

/SS/
Jesse P. Goode
Administrative Law Judge